UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PESTICIDES PROGRAMS

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John J. Jachetta, Ph.D
Regulatory Manager
Regulatory Success-America
Dow AgroSciences LLC
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Dear Dr. Jachetta:

The purpose of this letter is to advise you of the results of EPA's reevaluation of the terms of the phase-out of chlorpyrifos methyl (CPM). The reevaluation resulted from a meeting with representatives of USDA's Office of Pesticide Policy and others in March of this year where the USDA requested that the phase-out of Reldan 4E® be extended until Codex MRLs for alternatives were established. Further, they noted the effectiveness of combination products which include lower concentrations of CPM plus an alternative compound.

The Agency's 2001 decision on CPM provided a phase-out of the 43% liquid formulation end use product Reldan 4E®. Under the phase-out schedule, Dow AgroScience could sell, and distribute this product through December 31, 2003, and the last use date is December 31, 2004. The Agency recognized the importance of CPM to grain storage, particularly for on-farm storage and the smaller country elevators, and allowed for a phase-out in order to transition to alternative means of pest control. As a condition of the phase-out, EPA required additional studies to better characterize risk associated with CPM, and Dow AgroSciences has provided an acute delayed neurotoxicity study, and a two-generation rat reproduction study. These studies have been received and are currently being reviewed.

The Agency agreed in the IRED to reevaluate the phase-out in 2003 to determine if viable alternatives were available, and extend the phase-out if it were determined that no adequate alternatives were available. Since the IRED was signed, a few new chemicals have come on the market that are promising for stored grain. However, many of these new chemicals lack Codex MRLs, thus effectively limiting their use to crops that are not exported. Also, the Agency reevaluated its decision on whether the database for chlorpyrifos ethyl (CPY) was adequate to address data gaps for CPM.

The Agency has reconsidered the toxicity data gaps identified in the CPM Toxicology Chapter of the RED dated April 19, 2000, and concluded that CPM is likely to be less toxic than CPY based on a side-by-side comparison of cholinesterase inhibition levels in existing studies (See **Chlorpyrifos Methyl**: Status of Toxicity Data Gaps, Impact of New Data on the Risk Assessment and Impact on Cumulative Risk Assessment, July 8, 2003 which is attached). We have also concluded that given the structural similarities between the two chemicals, toxicity data generated using CPY could be used to address data gaps for CPM with the exception of the acute toxicity test requirements. CPM will continue to be regulated using its specific endpoints, and the 10x database uncertainty factor will be retained. This uncertainty factor is consistent with the 10x on CPY which is based on a weight-of-the evidence approach to sensitivity. EPA has also concluded that retaining CPM on stored grain will not have an impact on the Organophosphate Cumulative Risk Assessment.

Based on this information, the Agency has determined that the database for CPY is adequate to assess the risk associated with CPM, and CPM is eligible for reregistration. The CPY database addresses the data requirements for CPM with the exception of product-specific acute toxicity data.

The Agency will extend the phase-out of Reldan 4® through December 2004. According, the last date for sales and distribution of Reldan 4E® is December 31, 2004, and the last use date is December 31, 2005. This extension should allow time for the Codex MRLs that are currently in process for combination products containing CPM and cyfluthrin, and spinosad to be approved.

We intend to publish an amendment to the IRED and the Federal Register Notice of April 24, 2002, to inform all interested stakeholders of EPA's reevaluation of CPM in the near future. If you have any questions, please contact Jackie Mosby of my staff at (703)305-6792.

Sincerely,

Betty Shackleford, Acting Director
Special Review & Reregistration Division

Enclosures